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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/602,215 06/24/2003		Neema M. Kulkarni	PC 21501B	2258		
28880 7:	590 12/09/2005		EXAM	EXAMINER		
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD			COOK, R	COOK, REBECCA		
ANN ARBOR,		ART UNIT	PAPER NUMBER			
			1614	1614		
			DATE MAILED: 12/09/2005			

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application	n No.	Applicant(s)				
Office Action Summary		10/602,215 KULKAF		KULKARNI ET AL.	RNI ET AL.			
		Examiner		Art Unit				
		Rebecca (	<b>Cook</b>	1614				
	- The MAILING DATE of this communication app	ears on the	cover sheet with the co	orrespondence ad	dress			
Period fo	• •		0 57005 0 MONTH	O) OF THETA (0)	0) DAYO			
WHIC - Exter after: - If NO - Failur Any r	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DAYS IS IN A COMMENT OF THE MAILING DAYS IN A COMMENT OF THE M	ATE OF TH 36(a). In no ever vill apply and will cause the appl	IS COMMUNICATION int, however, may a reply be time I expire SIX (6) MONTHS from to ication to become ABANDONED	l. lety filed the mailing date of this ∞ 0 (35 U.S.C. § 133).				
Status								
1)⊠	Responsive to communication(s) filed on 29 Se	eptember 2	<i>005</i> .					
•	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.							
3)[	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims								
4) 又	4)⊠ Claim(s) <u>1-14,16 and 17</u> is/are pending in the application.							
•	4a) Of the above claim(s) is/are withdrawn from consideration.							
5)	Claim(s) is/are allowed.							
6)⊠	Claim(s) <u>1-14, 16, 17</u> is/are rejected.							
-	Claim(s) is/are objected to.							
8)□	Claim(s) are subject to restriction and/or	r election re	quirement.					
Applicati	on Papers							
9)[	The specification is objected to by the Examine	r.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority u	nder 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a)[	a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.							
	2. Certified copies of the priority documents have been received in Application No							
	3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.								
	ee the attached detailed Office action for a list of	or the certif	ica copies not received	u.				
Attachment	• •							
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)		4) Interview Summary ( Paper No(s)/Mail Da					
3) Infom	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date		5) Notice of Informal Pa		)-152)			

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#### **DETAILED ACTION**

Claims 1-14, 16 and 17 are pending and examined.

## Claim Rejections - 35 USC § 112

Claim17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants submit that claim 17 is fully supported in the specification as filed and does not introduce new matter. However, it is not seen that the specific limitations of the composition are recited in the specification, nor has Applicant pointed out where they may be found.

In view of the amendments to the claims the earlier rejection under 35 USC 112, paragraph one to enablement is withdrawn.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14,16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/59573 for the reasons given in the Office Actions of September 13, 2004, February 28, 2005 and June 17, 2005.

Applicants argue that WO 99/59573 does not suggest the limitations of polyhydric alcohol or pH in the composition or that said limitations would result in a stable liquid pharmaceutical composition. They further argue that Example 2 in WO 99/59573 shows that the addition of xylitol to gabapentin increases lactam formation and that it is the addition of glycine to gabapentin that decreases lactam formation, despite the presence of xylitol.

This is not persuasive, since the "comprising" language of the claims would allow for both xylitol and glycine as disclosed in WO 99/59573.

Applicants further argue that the Declaration under 37 CFR 1.132 submitted on May 27, 2005 provides stability data for a composition comprising 44 g glycerol and 30 g of xylitol per 100 ml of the composition. However, this is not stated in the Declaration. Furthermore, the Declaration does not compare stability data for the lower amount of polyhydric alcohol in instant composition with the amount of polyhydric alcohol in WO 99/59573.

### **Action Is Final**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pairdirect.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook

Primary Examiner

buealooh

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December 6, 2005